

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

**JAMES J. ELLIS, CLAUDIA B. CINQUANTI,
and SHARON L. PREZIOSO McLAUGHLIN,**

Plaintiffs,

V.

**APPLETON PAPERS, INC. and MOORE
BUSINESS FORMS, INC.,**

Defendants.

Consolidated civil actions

94-CV-558 (Lead)

94-CV-559 (Member)

94-CV-561 (Member)

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Norman A. Mordue, D.J.:

MEMORANDUM-DECISION AND ORDER

INTRODUCTION

Presently before the Court are two motions pursuant to Rule 702 of the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The first is a motion by both defendants (Dkt. No. 217) for an order precluding Kaye Kilburn, M.D., the expert witness retained by plaintiff Sharon L. Prezioso McLaughlin, from offering any expert testimony in support of McLaughlin's case. The second is a motion by both defendants (Dkt. No. 218) for an order precluding Jack D. Thrasher, Ph.D., the expert witness retained by plaintiffs James J. Ellis and Claudia B. Cinquanti, from offering any expert testimony in support of their claims. For the reasons set forth below, the Court grants both motions.

BACKGROUND

Amended consolidated complaint

In their amended consolidated complaint (Dkt. No. 60), filed on April 1, 1998, plaintiffs claim in general terms that between 1984 and 1993 they were employed by the Tompkins County Department of Social Services ("DSS"); that they worked in several office buildings including the building commonly known as "Biggs A Building"; that at all relevant times DSS purchased "carbonless copy paper" ("CCP") from defendants for use by DSS employees; that plaintiffs used CCP in a reasonably foreseeable manner for the purpose for which it was intended; and that plaintiffs were repeatedly exposed to CCP over a substantial length of time. Plaintiffs further claim: "The aforementioned CCP contained numerous chemicals and/or substances including, but

not limited to, formaldehyde; toluene diisocyanate; alkyl biphenyl; alkylated naphthelins; polyisocyanates; triisopropylbiphenols (TIPB's); and many other toxic and/or hazardous substances, which are poisonous, carcinogenic, deleterious, hazardous and otherwise harmful to human beings.” Plaintiffs allege that defendants knew or should have known that CCP contained these harmful toxic substances. Plaintiffs further allege that as a direct and proximate result of their prolonged and repeated exposure to CCP, they sustained serious personal injuries.¹ Plaintiffs set forth causes of action sounding in negligence, breach of implied warranty, breach of express warranty of fitness for a particular use, and strict products liability.

McLaughlin’s expert, Dr. Kilburn – generally

Plaintiff McLaughlin retained as her expert witness Kaye H. Kilburn, M.D., Ralph Edgington Professor of Medicine, University of Southern California Keck School of Medicine and Director of Environmental Sciences Lab. On January 24, 1997, Dr. Kilburn subjected McLaughlin to a battery of tests and prepared an expert report stating that she had “impairments” which were “attributed to carbonless copy paper over years.” On January 2, 2002, after further testing, he reported to her attorney a diagnosis of “chemical encephalopathy ... due to carbonless copy paper.” At his deposition on November 4, 2004, he attributed McLaughlin’s symptoms to chemical encephalopathy caused by formaldehyde released from the CCP she used during her employment at DSS from 1984 to 1993.

Ellis’ and Cinquanti’s expert, Dr. Thrasher – generally

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The injuries allegedly sustained are variously referred to by plaintiffs as multiple chemical sensitivities (“MCS”), chemical encephalopathy, toxic encephalopathy, immune dysregulation, and building-related illness. Essentially, the theory is that exposure to formaldehyde causes neurological and/or immune-system injury which renders the patient hypersensitive to common chemicals that do not cause ill effects in most people.

Dr. Thrasher, the expert witness retained by plaintiffs Ellis and Cinquanti, proposes to testify that these two plaintiffs suffer from building-related illness as a consequence of their use of CCP while employed by DSS. Both worked at DSS from 1984 to 1993. Dr. Thrasher's report, dated January 8, 2002, characterized Ellis' and Cinquanti's complaints as building-related illness caused by exposure, during their employment at DSS, to indoor contaminants including CCP. He concluded that the CCP forms emitted formaldehyde sufficient to cause Ellis' and Cinquanti's alleged building-related illnesses.

These motions

Defendants, who have engaged in discovery and deposed Drs. Thrasher and Kilburn, move to preclude them from offering expert testimony at trial or in any other proceeding in these cases. Defendants base their motions on Rule 702 of the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). They contend that the proffered expert testimony does not reflect reliable, scientific knowledge derived by the scientific method. They further contend that the experts have not properly applied their scientific theories to the facts of the cases.

APPLICABLE STANDARD

It is fundamental that only relevant evidence is admissible at trial. *See* Fed. R. Evid. 402. "Relevant evidence" is defined as "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401.

Where expert testimony is offered, the trial court must ensure not only that the testimony is relevant, but also that it "rests on a reliable foundation." *Amorgianos v. National R.R. Passenger Corp.*, 303 F.3d 256, 265 (2d Cir. 2002) (quoting *Daubert*, 509 U.S. at 597). In this

regard, Rule 702 of the Federal Rules of Evidence provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The *Daubert* court observed that the inquiry envisioned by Rule 702 is “a flexible one.”

509 U.S. at 594. “Its overarching subject is the scientific validity – and thus the evidentiary

relevance and reliability – of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.” *Id.* at 594-95.

A district court is not required to admit opinion evidence that is connected to existing data “only by the *ipse dixit* of the expert.” *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). “A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.” *Id.* As the court in *Amorgianos* stated, “when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony.” 303 F.3d at 266.

With respect to the reliability of a general theory propounded by an expert, the *Daubert* court “has identified a number of factors bearing on reliability that district courts may consider, such as (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) a technique's known or potential rate of error, and the existence and maintenance of standards controlling the technique's operation; and (4) whether a particular technique or theory has gained general acceptance in the

relevant scientific community.” *Amorgianos*, 303 F.3d at 266 (citations and internal quotes omitted).

DISCUSSION

Dr. Kilburn

It is Dr. Kilburn’s opinion that plaintiff McLaughlin was exposed to formaldehyde through her contact with CCP and that this exposure caused chemical encephalopathy, which is the source of her symptoms.² Upon thorough review of the record, including the transcripts of Dr. Kilburn’s depositions, this Court has no difficulty in concluding that Dr. Kilburn’s proffered opinion is not admissible under Rule 702 and *Daubert*.

First, Dr. Kilburn’s general theory that exposure to formaldehyde in CCP can cause chemical encephalopathy is not the product of reliable scientific principles and methods. Second, with respect to Dr. Kilburn’s application of his general theory to the specific facts of McLaughlin’s case – even accepting the highly questionable proposition that she suffers from chemical encephalopathy or a similar condition³ – there is no showing that her condition was

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McLaughlin’s complaints as reported by Dr. Kilburn in 2002 include loss of balance, extreme fatigue, lack of concentration, recent and long-term memory loss, finger nail changes, dryness of mouth, nose and throat, throat irritation, reduced sense of smell and loss of appetite.

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In this respect, it is significant that Dr. Kilburn is an internist, not a neurologist. On January 2, 2002, he reported that as a result of the tests he administered to McLaughlin, he found the following abnormalities: “abnormal slowing of simple and choice reaction time, abnormal blink reflex slowing on the right, diminished to abnormal visual field performance in the right eye[] with scotomata in both eyes, absent lower extremity vibration and abnormal digit symbol.” Dr. Kilburn counted these as seven total abnormalities and concluded that this “exceeds the allowable 0-2 abnormalities ... in people unexposed to chemicals.”

Defendants rely on reports by Roy DeHart, M.D., Medical Director, Division of Corporate Health, Vanderbilt Medical Center, and Barry Gordon, M.D., Ph.D., Professor of Neurology

caused by formaldehyde from CCP.

Daubert factors

In addressing Dr. Kilburn's general theory that exposure to formaldehyde from CCP can cause chemical encephalopathy, the Court considers the *Daubert* factors as summarized in *Amorgianos*, that is, (1) whether the theory upon which Dr. Kilburn bases his opinion can be and has been tested; (2) whether it has been subjected to peer review and publication; (3) its known or potential rate of error, and the existence and maintenance of standards controlling its operation; and (4) whether the theory has gained general acceptance in the relevant scientific community. *See* 303 F.3d at 266. These factors are not determinative; rather, they assist the Court in evaluating the reliability of the proffered opinion.

With respect to the first *Daubert* factor – whether the theory can be and has been tested – defendants demonstrate that Dr. Kilburn's general theory that formaldehyde from CCP can cause chemical encephalopathy has never been tested. Barry Gordon, M.D., Ph.D., Professor of Neurology and holder of the Cognitive Neuroscience Chair at Johns Hopkins Medical Institutions states flatly: "Dr. Kilburn's theory regarding the mechanism is unsupported, unvalidated and untested and is merely a speculative hypothesis subscribed by him alone." Dr. Gordon explains that Dr. Kilburn's theory cannot be tested because it is not based on generally-accepted scientific methods. Dr. Gordon supports this assertion fully in his affidavit. He avers that the battery of tests Dr. Kilburn used "is not generally accepted by even a minority of the relevant scientific and medical communities of neurology and neuropsychology as being able to determine whether individuals suffered neurologic and/or neuropsychologic injuries, nor whether these alleged

and holder of the Cognitive Neuroscience Chair at Johns Hopkins Medical Institutions. Both examined McLaughlin and concluded that she had no neurological impairment.

injuries are due to any allegedly toxic agent or agents.” Dr. Gordon explains specific flaws in Dr. Kilburn’s methods, such as using reference values that are not generally accepted, not utilizing a proper control group, and not using an accepted statistical method to identify abnormalities.

McLaughlin has adduced no scientific studies or tests supporting Dr. Kilburn’s theory or methods. In his September 24, 2003 deposition, Dr. Kilburn asserts that his theory of causation should be accepted because he is an expert. Similarly, McLaughlin argues that Dr. Kilburn’s opinion is based on his years of clinical experience in testing and treating patients with chemical encephalopathy, by research of his own and others in the field of chemical sensitivity, and by the specifics of plaintiff’s case. For example, in his January 2, 2002 report, Dr. Kilburn describes the abnormalities found in his testing of McLaughlin and states that “these abnormalities are similar to those seen in the previous patients who shared this exposure.” He also relies on the temporal proximity of McLaughlin’s use of CCP and the onset of her symptoms. These grounds for his opinion are manifestly subjective and cannot be subjected to testing or studies. The Court finds, with respect to the first *Daubert* factor, that Dr. Kilburn’s theory cannot be and has not been tested.

The second *Daubert* factor is whether the theory has been subjected to peer review and publication. Defendants demonstrate without contradiction that peer-reviewed medical literature does not support Dr. Kilburn’s general theory that formaldehyde from CCP can cause chemical encephalopathy. Dr. Gordon’s affidavit explains that none of the articles or reference works cited by Dr. Kilburn in his depositions supports the theory that exposure to formaldehyde through the use of CCP causes brain or nerve damage. Dr. Gordon adds that in his own research he has found no literature to support this theory.

Similarly, William J. Waddell, M.D., Professor and Chairman, Emeritus, of the

Department of Pharmacology and Toxicology at the University of Louisville School of Medicine, points out that in 2000, the National Institute of Health and Human Services (“NIOSH”) issued a “Hazard Review” pertaining to CCP. This publication reviewed the known literature on CCP and was peer-reviewed by more than 20 specialists. Although it recognized the presence of formaldehyde in CCP, it established that there is no scientific evidence that medical problems such as those described by plaintiffs are caused by exposure to CCP.

Dr. Kilburn does not contend that the theory that exposure to CCP can cause chemical encephalopathy exists anywhere in peer-reviewed medical literature. Rather, he simply states that it is known that CCP contains formaldehyde, and it is known that formaldehyde can cause harm. This proposition falls far short of supporting his theory that formaldehyde is emitted from CCP in such a manner that it can cause chemical encephalopathy in people who work with or around CCP.

The Court turns to the third *Daubert* factor, *i.e.*, the theory’s known or potential rate of error, and the existence and maintenance of standards controlling its operation. Dr. Gordon spells out in detail the basis for his view that Dr. Kilburn’s methods fail to conform to acceptable scientific practices. The evidence fully supports Dr. Gordon’s conclusion that, as a result of this failure, there is no known potential rate of error and customary standards cannot be applied to Dr. Kilburn’s methods.

The final *Daubert* factor is whether the theory is generally accepted in the relevant scientific community. Dr. Waddell asserts: “There is no scientific evidence that medical problems such as those described by these plaintiffs are caused by exposure to CCP.” Dr. Waddell sets forth in detail the basis for this conclusion. Moreover, he explains that Dr. Kilburn’s own conclusions are undermined by a number of defects in his methods, including his

failure to apply generally accepted scientific standards in assigning a causal connection between McLaughlin's symptoms and her alleged formaldehyde exposure from CCP.

In the same vein, Dr. Gordon asserts:

There is no evidence, in either Dr. Kilburn's studies or in the world's medical/scientific literature, that exposure to formaldehyde allegedly emitted by carbonless copy paper causes neurologic or neuropsychologic abnormalities of the kind that Dr. Kilburn claims. There is no medical or scientific evidence supporting general causation for such neurologic or neuropsychologic abnormalities by carbonless copy paper.

There is no accepted medical or scientific explanation of the mechanism whereby formaldehyde allegedly off-gassed from carbonless copy paper could cause systemic neurologic damage.

These assertions are fully supported by the record evidence, including the evidence discussed above regarding lack of peer-reviewed literature and failure to apply accepted scientific methods.

Dr. Kilburn's general theory that chemical encephalopathy is caused by formaldehyde in CCP does not satisfy the four *Daubert* factors.

Differential diagnosis

It is true that, as McLaughlin argues, the four *Daubert* factors discussed above do not constitute a "definitive checklist or test." *Daubert*, 509 U.S. at 593. Nevertheless, there must be some basis for the Court to find that Dr. Kilburn's testimony is the product of reliable scientific principles and methods which have been applied reliably to the facts of the case. *See generally* Fed. R. Evidence 702. McLaughlin contends that this requirement is fulfilled by Dr. Kilburn's method of "differential diagnosis."

Differential diagnosis is explained by the Fourth Circuit as follows:

Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated. A reliable differential diagnosis typically, though not invariably, is performed after physical examinations, the taking of medical histories,

and the review of clinical tests, including laboratory tests, and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely. This technique has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results.

Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999) (citations and internal quotes omitted); see *McCulloch v. H.B. Fuller Co.*, 61 F.3d 1038, 1043-44 (2d Cir. 1995). A differential diagnosis typically goes to the question of specific causation rather than general causation.⁴

When asked in defendant's interrogatories to describe his differential diagnosis, Dr. Kilburn responded:

A careful differential diagnosis that considered other possible causes for brain impairment found none and brought attribution of impairments to chemical exposure to formaldehyde from CCP. The differential diagnosis of diffuse brain damage that is considered includes 1) Alzheimer's disease, and associated syndromes of progressive loss of mind (dementia), 2) postural and movement disorders exemplified by Parkinson's disease and related syndromes that blend into muscular weakness disorders of 3) amyotrophic lateral sclerosis (Lou Gehrig's disease) and motor neuron disease, syndromes of progressive ataxia (movement disorders) and 4) progressive blindness and 5) neurosensory deafness. Another disease group of lesser frequency is multiple sclerosis with a variable speed of progression and other demyelinating diseases that have more rapid course.

These neurological diseases all have distinctive clinical signs and the absence of these

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See, e.g., *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005), noting that differential diagnosis does not ordinarily support an opinion on general causation. This is because a differential diagnosis is based on the assumption that the causes to which the elimination process is applied are actually capable of causing the injury. The Second Circuit added:

We cannot say that a differential diagnosis may never provide a sufficient basis for an opinion as to general causation. There may be instances where, because of the rigor of differential diagnosis performed, the expert's training and experience, the type of illness or injury at issue, or some other case-specific circumstance, a differential diagnosis is sufficient to support an expert's opinion in support of both general and specific causation.

Id. The Court finds no case-specific circumstance in the case at bar that would render Dr. Kilburn's purported differential diagnosis sufficient to support general causation.

contrasts with impairment of many brain functions and areas from chemicals such as formaldehyde. For example, muscle tremors, rigidity and ataxic gait distinguish Parkinson's disease. Alzheimer's has memory loss and personality change attributed to the brain's loss of inhibition from frontal lobe. The absence of exposures to alcohol, lead, mercury and other classic and newer poisons like organophosphates rules out the classic encephalopathies, brain damage, due to poisons.

The weaknesses in this analysis are obvious. Even assuming that McLaughlin does suffer from chemical encephalopathy, there is no scientific support for the proposition that formaldehyde from CCP is a possible cause of her condition, nor is there a valid basis to eliminate other possible causes. As stated by the Second Circuit in *Ruggiero*: "Where an expert employs differential diagnosis to rule out other potential causes for the injury at issue, he must also rule in the suspected cause, and do so using scientifically valid methodology." 424 F.3d at 254 (emphasis added; citation and internal quotes omitted).

Here, there is no sound basis to "rule in" CCP as a probable cause, either of chemical encephalopathy in general or of McLaughlin's condition specifically. The lack of scientific support for the general proposition that exposure to formaldehyde from CCP can cause chemical encephalopathy has been discussed above. Further, there is a complete lack of scientific support for the specific proposition that exposure to formaldehyde from CCP was a possible cause of McLaughlin's condition. Dr. Kilburn had no knowledge regarding which of the dozens of types of CCP paper McLaughlin was exposed to, nor did he know how many CCP forms she used on a daily basis. Compare *McCulloch*, 61 F.3d at 1042-43 (in addition to her medical expert's differential diagnosis, plaintiff adduced evidence from an engineering expert in support of her claim that her work area was "in the breathing zone" of the harmful fumes). When asked about the level of her exposure, he said: "She told me she was exposed, so I didn't pursue it." He did not test the air quality where McLaughlin worked, nor did he

take into account the air quality tests that had been performed by others. Indeed, tests performed by industrial hygienists in plaintiff's workplace in 1993 detected no appreciable amounts of formaldehyde.

Moreover, even assuming that McLaughlin does suffer from chemical encephalopathy and that formaldehyde from CCP is ruled in as a possible cause of her condition, there is no reasonable basis to rule out other possible causes so as to render formaldehyde from CCP the most likely cause. Dr. Kilburn's elimination of major neurological disorders such as Alzheimer's or Parkinson's disease is of little assistance in ruling out possible causes of chemical encephalopathy. Dr. Kilburn's statement that "[t]he absence of exposures to alcohol, lead, mercury and other classic and newer poisons like organophosphates rules out the classic encephalopathies, brain damage, due to poisons" is far too general and conclusory to rule out other possible causes of McLaughlin's alleged chemical encephalopathy so as to render CCP the most probable. Indeed, at one point in his deposition, Dr. Kilburn conceded that it was "a distinct possibility" that any chemical that could be inhaled could induce chemical encephalopathy under certain conditions. He acknowledged that his assumption that CCP was McLaughlin's "only significant chemical exposure" was based solely on the "[h]istory given by patient." He admittedly did not evaluate other possible workplace sources of formaldehyde or other chemicals, such as the carpeting of which McLaughlin initially complained, or paint or building materials from the ongoing office renovation work, although he agreed that they could be a source of formaldehyde. The record clearly demonstrates that Dr. Kilburn's conclusion that formaldehyde from CCP is the most likely cause for McLaughlin's chemical encephalopathy is based on unsupported speculation.

In sum, even accepting that McLaughlin sustained chemical encephalopathy, there is

no sound basis to find that formaldehyde from CCP is one possible cause of her condition, nor is there a sound basis to rule out other possible causes such that formaldehyde from CCP is the most likely cause. Dr. Kilburn's purported differential diagnosis does not support his opinion that McLaughlin's alleged chemical encephalopathy was caused by exposure to formaldehyde from CCP. Nor is there any other scientifically valid support for this opinion.

Dr. Kilburn – conclusion

Citing the Second Circuit decision in *McCullock*, McLaughlin argues that “[d]isputes as to the strength of [an expert’s] credentials, faults in his use of differential etiology as a methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony.” 61 F.3d at 1044. However, to the extent that *McCullock* may be read to hold that the lack of scientific support for an expert’s opinion goes to weight, not the admissibility of his testimony, it is no longer good law. In *Ruggiero*, the Second Circuit observed that such a reading of *McCullock* “is precluded by the Supreme Court’s subsequent decision in *Joiner* [522 U.S. at 146].” 424 F.3d at 255. The *Ruggiero* court added: “Following *Joiner*, we held that ‘when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony.’” 424 F.3d at 255 (citing *Amorgianos*, 303 F.3d at 266).

This Court concludes that the data and methodology on which Dr. Kilburn relies are wholly inadequate to support the conclusions he reaches. Thus, his expert testimony is unreliable and irrelevant, and *Daubert* and Rule 702 mandate its exclusion. Accordingly, in the exercise of its discretion, the Court grants defendants’ motion and precludes Dr. Kilburn’s expert testimony for all purposes.

Dr. Thrasher

Jack D. Thrasher, Ph.D., the expert witness retained by plaintiffs Ellis and Cinquanti, describes himself as a “Toxicologist/Immunotoxicologist.” Dr. Thrasher proposes to testify that Ellis and Cinquanti were exposed to formaldehyde through their contact with CCP during their employment at DSS, and that this exposure caused building-related illness, which is the source of their symptoms.⁵ His January 8, 2002 report characterized Ellis’ and Cinquanti’s complaints as building-related illness caused by exposure to indoor contaminants during their employment at DSS, and stated that the most likely sources of these contaminants were unvented photocopy machines, new carpeting, CCP, remodeling, steam containing diethylaminoethanol, and probable microorganisms. He concluded that the CCP forms emitted formaldehyde sufficient to cause Ellis’ and Cinquanti’s alleged building-related illnesses.

Upon thorough review of the record, this Court easily concludes that Dr. Thrasher’s proffered opinion is not admissible under Rule 702 and *Daubert*. First, Dr. Thrasher’s general theory that exposure to formaldehyde in CCP can cause building-related illness suffers from many of the same shortcomings as Dr. Kilburn’s theory and is not the product of reliable scientific principles and methods. Second, even accepting the highly questionable proposition

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Cinquanti’s interrogatory responses claim she suffers from muscle aches through her entire body, constant headaches, upper respiratory infections, fever, swollen glands, sore throat, loss of voice, constant hacking cough, burning eyes, disorientation, neurological damage, shortness of breath, constant fatigue, chest pain, sinus burning and pressure, memory loss, cracked and bleeding fingers, blurred vision and a problem of transposition of letters.

Ellis stated in his interrogatories that he suffers from back pain, that when exposed to carbonless copy paper or its constituents he feels that he is having a heart attack; that he has facial pain, severe headaches, and pain in his joints; and that after a severe exposure he has attacks of vomiting and muscle spasms.

that Ellis and Cinquanti suffer from building-related illness or any similar condition,⁶ there is no valid scientific evidence that their conditions were caused by formaldehyde from CCP.

Daubert factors

In addressing Dr. Thrasher's theory that exposure to formaldehyde from CCP can cause building-related illness, the Court considers the *Daubert* factors as summarized in *Amorgianos*, that is, (1) whether the theory upon which Dr. Thrasher bases his opinion can be and has been tested; (2) whether it has been subjected to peer review and publication; (3) its known or potential rate of error, and the existence and maintenance of standards controlling its operation; and (4) whether the theory has gained general acceptance in the relevant scientific community. *See* 303 F.3d at 266.

Defendants demonstrate with respect to the first *Daubert* factor that Dr. Thrasher's general theory that formaldehyde from CCP can cause building-related illness has never been tested. Defendants rely primarily on the affidavit of Dr. Waddell, which explains the lack of scientific support for the theory and the resultant absence of tests and studies. Dr. Waddell's affidavit also addresses the second *Daubert* factor and supports defendants' position that the theory has not been subjected to peer review and publication. With respect to the third *Daubert* factor, defendants have shown that as a result of the failure of Dr. Thrasher's

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In this respect, the Court notes that Dr. Thrasher is not a medical doctor and has not met either Ellis or Cinquanti. Although he interviewed Ellis by telephone, he has never spoken to Cinquanti.

In contrast, defendants submit the detailed reports of Roy DeHart, M.D., Medical Director, Division of Corporate Health, Vanderbilt Medical Center, and Barry Gordon, M.D., Ph.D., Professor of Neurology and holder of the Cognitive Neuroscience Chair at Johns Hopkins Medical Institutions. They both conducted examinations of these two plaintiffs and reviewed their records. They concluded that neither Ellis nor Cinquanti had any neurological abnormalities or impairments.

methods to conform to acceptable scientific practices, there is no known potential rate of error and customary standards cannot be applied to his methods. And finally, defendants have established that Dr. Thrasher's theory is not generally accepted in the relevant scientific community. This is accomplished primarily by Dr. Waddell's affidavit and the sources he cites.

In response, Ellis and Cinquanti submit a Memorandum of Law with over 600 pages of attachments, including the "Toxicological Profile for Formaldehyde" prepared by United States Department of Health and Human Services, Public Health Service Agency for Toxic Substances and Disease Registry, and the NIOSH Hazard Review pertaining to Carbonless Copy Paper. A close reading of the Memorandum of Law and the cited portions of the attachments reveals that not a single source subscribes to the theory that formaldehyde from CCP can cause the type of building-related illness claimed here. There are a few reports of transient acute responses to CCP such as skin irritation; there is a reference to unproven "claims" that routine use of CCP can cause neurological damage; there is evidence that at least some CCP contains formaldehyde; there is evidence of the dangers of formaldehyde – but, even considering "the totality of the scientific evidence presented" as these plaintiffs ask the Court to do, the Court finds no support in these publications for the theory that formaldehyde emitted from CCP poses a danger of the type alleged by these two plaintiffs.

The Court acknowledges, as is asserted in Ellis' and Cinquanti's Memorandum of Law, that lack of epidemiological support is not necessarily fatal to a proffer of expert testimony, and that reliability may be established in a number of ways. There must, however, be some sound scientific basis for the expert's opinion. Here, not only are there no scientific tests or controlled studies demonstrating a causal link between CCP and building-related

illness, there is no evidence whatsoever demonstrating such a link. The record contains a few anecdotal case reports and Dr. Thrasher's own conclusions to the effect that formaldehyde exposure can be harmful, but even Dr. Thrasher's studies do not specifically address CCP, and there is no evidence that CCP releases any amount of formaldehyde, let alone enough to do harm. The Court concludes that there is no reliability to Dr. Thrasher's theory of general causation, *i.e.* that exposure to formaldehyde in CCP can cause building-related illness.

Specific causation

Even if there were a sound basis for Dr. Thrasher's general theory that exposure to formaldehyde in CCP can cause building-related illness, his testimony would be inadmissible due to lack of evidence of specific causation in the particular cases in issue. It is undisputed that he had no specific information about the CCP used by Ellis and Cinquanti; that he performed no testing of CCP, nor did he rely on tests by others; that he did not evaluate other possible workplace sources of their symptoms; that he did not test the air quality where they worked; and that he did not take into account the air quality tests that had been performed by others, which in fact detected no appreciable amounts of formaldehyde. Nor did he address the significant other potential causes for Ellis' and Cinquanti's symptoms that appear in their medical records.

Dr. Thrasher – conclusion

The data and methodology on which Dr. Thrasher relies "are simply inadequate to support the conclusions reached[.]" *Amorgianos*, 303 F.3d at 266. As such, his expert testimony is unreliable and irrelevant, and *Daubert* and Rule 702 mandate its exclusion. *See id.* Accordingly, in the exercise of its discretion, the Court grants defendants' motion and precludes Dr. Thrasher's expert testimony for all purposes.

CONCLUSION

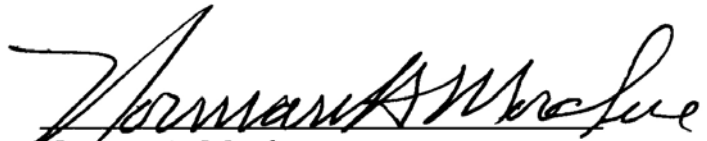
It is therefore

ORDERED that defendants' motion (Dkt. No. 217) for an order precluding Kaye Kilburn, M.D., the expert witness retained by plaintiff Sharon L. Prezioso McLaughlin, from offering any expert testimony in this case, is granted; and it is further

ORDERED that defendants' motion (Dkt. No. 218) for an order precluding Jack D. Thrasher, Ph.D., the expert witness retained by plaintiffs James J. Ellis and Claudia B. Cinquanti, from offering any expert testimony in this case, is granted.

IT IS SO ORDERED.

February 14, 2006
Syracuse, New York


Norman A. Mordue
U.S. District Judge